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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,232	08/26/2003	Edward P. Ingenito	10991-002004	6203

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EXAMINER	
WILLIAMS, CATHERINE SERKE	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,232	INGENITO, EDWARD P.	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/26/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 recites "the fibrinogen and fibrinogen activator are administered separately"; however, claim 1, from which claim 7 ultimately depends, recites "administering...an anti-surfactant **composition**". [Emphasis added] According to claim 5 (from which claim 7 directly depends, fibrinogen and the fibrinogen activator are components or precursors to the composition that is recited in claim 1. Since claim 1 positively sets forth administering the composition, the term composition inherently indicates that the components or precursors have already been formed into the composition. Therefore, the step of administering separately in claim 7 would be a different method of administering the fibrinogen and fibrogen activator. A method of administering the composition and also administering them separately is not supported or taught by the specification and in fact could not be performed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 13-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2,5-8,14-16 and 19-24 of U.S. Patent No. 6,682,520. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is a broader recitation of the same invention. Many of the limitations are identical and if not identical then obvious. Specifically, claim 1 of the instant application claims "administering by way of the patient's trachea to the target region of the lung" reads on "advancing a bronchoscope into a region of the lung targeted" of claim 1 of the above patent. Likewise, "an anti-surfactant composition" includes "the biological or biochemical material" of claim 1 "comprises fibrin or fibrinogen" of claim 2. Fibrin or fibrinogen are known anti-surfactants in the art. All of the dependant claims can be found in either the independent or dependant claims of the above patent.

Claims 7-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,682,520 in view of Edwardson et al (US Pat# 5,739,288). Pat# 6,682,520, specifically claims 1-2, is encompassed by the claims listed above (1,2 and 5) but fails to include the concentrations of fibrin as listed in claims 7-11. However, Edwardson discloses a fibrin sealant composition that can be used for

sealing tracheal and bronchial anastomoses and air leaks or lacerations of the lung (promoting fibrosis) that includes fibrinogen, thrombin, clot promoting factor XIIIa and antibiotics. Edwardson states that the concentration of the fibrin monomer be no less than about 10 mg/ml, more preferably from about 20 mg/ml to about 200 mg/ml, even more preferably from about 20 mg/ml to about 100 mg/ml and most preferably from about 25 mg/ml to about 50 mg/ml.

Since the invention of Pat# 6,682,520 is drawn to closing a region of the lung by gluing tissue (see 10:40) and Edwardson teaches a composition to enhance the closure of leaks or lacerations of the lung (i.e. a tissue sealant) a combination is proper. At the time of the invention, it would have been obvious to use the fibrin sealant of Edwardson in order to provide an enhanced fibrin formulation for tissue closure thereby improving patient recovery time.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine S. Williams
July 22, 2004

MICHAEL J. HAYES
PRIMARY EXAMINER